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## **Randomised trial of infant sleep location on the postnatal ward**

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## ABSTRACT

**Objective:** To determine whether postnatal mother-infant sleep proximity affects breastfeeding initiation and infant safety.

**Design:** Randomised non-blinded trial analysed by intention to treat.

**Setting:** Postnatal wards of the Royal Victoria Hospital (RVI), Newcastle-upon-Tyne.

**Participants:** 64 newly delivered mother-infant dyads with a prenatal intention to breastfeed (vaginal deliveries, no intra-muscular / intra-venous opiate analgesics in preceding 24 hours).

**Intervention:** Infants were randomly allocated to one of 3 sleep conditions: Baby in mother's bed with cot-side; baby in side-car crib attached to mother's bed; baby in stand-alone cot adjacent to mother's bed.

**Main outcome measures:** Breastfeeding frequency and infant safety observed via night-time video-recordings.

**Results:** During standardised 4-hour observation periods bed and side-car crib infants breastfed more frequently than stand-alone cot infants [mean difference (95% CI): bed vs stand-alone cot =2.56 (0.72-4.41); side-car crib vs stand-alone cot =2.52 (0.87-4.17); bed vs. side-car crib = 0.04 (-2.10-2.18)]. No infants experienced adverse events, however bed infants were more frequently considered to be in potentially adverse situations [mean difference (95% CI): bed vs stand-alone cot 0.13 (0.03-0.23); side-car crib vs stand-alone cot 0.04 (-0.03-0.12); bed vs side-car crib 0.09 (-0.03-0.21)]. No differences were observed in duration of maternal or infant sleep, frequency or duration of assistance provided by staff; or maternal rating of post-natal satisfaction.

**Conclusion:** Suckling frequency in the early post-partum period is a well known predictor of successful breastfeeding initiation. Sleeping newborn babies in close proximity to their mothers (bedding-in) facilitates frequent feeding in comparison with rooming-in. None of the 3 sleep conditions was associated with adverse events; although infrequent, potential risks may have occurred in the bed-group. Side-car cribs are effective in enhancing breastfeeding initiation and preserving infant safety on the post-natal ward.

**Key words:** Bedding-In; Rooming-In; Side-car crib; Breastfeeding initiation; Infant safety; Post-natal care.

Abstract word count = 281

### *What is already known on this topic?*

- Frequent suckling and skin-to-skin contact following delivery enhances breastfeeding initiation, and mother-infant sleep contact is commonly practiced in the home by breastfeeding mothers
- Rooming-in facilitates breastfeeding on demand in comparison with nursery care, but does not permit continuous mother-infant contact or spontaneous suckling

### *What this study adds:*

- Examines two forms of mother-infant sleep contact (baby-in-bed and side-car crib) on postnatal ward and demonstrates increased night-time feed frequency in bed and side-car crib conditions where mother and infant experience unhindered access
- Use of side-car cribs on post-natal ward increases breastfeeding frequency while maintaining infant safety.

## **INTRODUCTION**

Although the beneficial effects of early and frequent suckling and skin-to-skin contact on breastfeeding initiation are well known [1-6] there has been little work on the effect of subsequent mother-infant contact in the first postnatal days. Night-time rooming-in has been shown to enhance breastfeeding on demand in comparison with night-time nursery-care [7, 8]; however 'rooming-in' involves babies sleeping in stand-alone cots that do not permit continuous contact or spontaneous feeding between mothers and infants. Yet such contact may be of importance for mothers to understand their babies' signals and to respond effectively.

Unhindered contact can only be provided for mother and baby at night on the post-natal ward through some arrangement whereby mother and baby can maintain continuous contact to allow spontaneous breastfeeding. Two forms of bedding-in currently practised in UK hospitals involve either sleeping the baby in the mother's bed, usually with the provision of removable cot-sides to prevent falls; or sleeping the baby in a side-car crib that attaches to the frame of the mother's bed and is enclosed on three sides, allowing the baby a separate sleep surface, but one that is contiguous with the mother's bed. We also recognised that breastfeeding mothers commonly take their babies into their own beds for feeding, and that both parties often fall asleep in this situation, whether or not this was planned, or advised against by midwives, or whether appropriate cot sides were provided.

We therefore designed a trial to determine the way in which different degrees of mother-infant contact in the immediate postnatal period affects infant care, including breastfeeding, and to ascertain whether infant safety is compromised when babies and mothers are in close proximity.

## **METHODS**

### **Recruitment**

Following approval from the research ethics committee we recruited pregnant women attending ante-natal breastfeeding workshops (held once or twice per month) in Newcastle upon Tyne, UK. Those returning completed consent and enrolment forms were entered into the trial if they were healthy, non-smoking first-time mothers, pregnant with a single infant, anticipating a normal vaginal delivery and intending to breastfeed.

### **Assignment**

Recruits were randomly allocated, by a concealed sequence compiled with a random number generator, to one of three sleep conditions: rooming-in with standalone cot; bedding-in with a side-car crib; or bedding-in in mother's bed with cot side. Recruitment, enrolment and anonymous randomisation were conducted by three different members of the research team (KB, EH and SL respectively). Post-partum exclusion criteria included caesarean delivery, ill baby or mother, and receipt of intra-venous or intra-muscular opiate analgesics in the preceding 24 hours. Following delivery the research nurse confirmed each mother's continuing eligibility and willingness to participate in the study.

### **Video protocol**

A small camcorder with infra-red filming capability was erected atop a two metre monopod attached to the foot of the mother's bed with the recorder housed in an attaché case placed under the bed. Mothers were provided with a remote control and requested to start the recording whenever they intended to settle down for sleep. The tape recorded for 8 hours or until the mother chose to terminate filming. Mothers were requested to keep their baby in the allocated sleep location while they were asleep. We did not specify how or where mothers should feed their infants. Mothers and babies were filmed on the first two postnatal nights.

Following filming we offered mothers the opportunity to view their video-tapes as per standard guidelines [9] and obtained further consent for the videos to be analysed. Mothers then participated in a semi-structured interview regarding their postnatal experience, and we abstracted labour and delivery information from the case notes. Upon completion of the study mothers received a £10 gift voucher for baby products and a tape of clips from their 2 nights of filming (approved by the Local NHS Research Ethics Committee). We report here on the short-term outcomes.

### **Masking**

We described the study as an infant sleep study to investigate effects of the three conditions on the postnatal experience generally. True blinding was not possible either for investigators or participants.

### **Outcome measures**

The outcome on which we powered the study was successful initiation of breastfeeding, defined on the basis of observed infant behaviour (attempted feeds, successful feeds, feeding effort), but we regarded infant safety as a second primary outcome even though there was no published or unpublished data on which to base a power calculation. Feeding effort was calculated as the frequency per hour of unsuccessful and successful feeding attempts. Infant safety was determined by assessing 'potential risk exposure': frequency per hour and proportional duration of potentially adverse situations categorised as breathing risk (external airways covered); overheating risk (head completely covered); falling risk (precarious positioning with no means of fall prevention); entrapment risk (wedged between bed and side-rail); and overlaying risk (trapped under mother's torso). Infant safety was monitored according to the hospital's extant bedding-in policy involving regular checks on mothers and infants known to be bedding-in.

Other outcome measures were maternal and infant sleep duration, maternal satisfaction, and staff contact time with the mother.

### **Sample size**

Previous studies of mother-infant sleep contact had found that night-time breastfeeding frequency was three-times greater when mothers and infants slept in the same bed in comparison to separate sleep locations [10]. In order to observe a difference between bedding-in (bed or side-car crib conditions) and rooming-in (stand-alone cot condition) we used short-term outcomes (feed frequency) as the basis for our power calculations: 28 participants were required in each group to achieve 90% power at 95% precision. To achieve 80% power at the same precision, each group required 20 participants. We aimed, therefore, to obtain data on 90 mother-infant pairs (30 allocated to each arm of the trial), however as half of all mothers recruited were lost due to ineligibility following delivery 64 mother-infant pairs participated in the intervention.

### **Analysis**

The video tapes of mother-infant behaviour on the first and second postnatal nights were coded using Noldus Observer 5 behavioural analysis software at the University of Durham Parent-Infant Sleep Lab, employing behavioural taxonomies developed in previous studies.[11] Three researchers coded the video tapes, coding equal proportions of tapes from each condition in order to minimise any potential observer bias. Inter- and intra-observer reliability was regularly tested via re-coding of identical sections of tape to ensure kappa scores greater than 90%. Statistical analyses were conducted using SPSS: all analyses employed pair-wise comparisons between the conditions using parametric or non-parametric tests according to whether or not the data were normally distributed.

## RESULTS

### Recruitment rate

Fifteen to 20 pregnant women participated in each of the 35 breastfeeding workshops attended; a mean of 4.1 women from each workshop volunteered for the study. Not all of the women attending workshops were eligible to volunteer for the trial (multiple pregnancies, scheduled c-sections, planned opiate analgesia, planned home delivery) which we estimate reduced the pool of potential volunteers to a mean of 11.5 women per workshop, resulting in an approximate recruitment rate of 35%. We were not able to compare characteristics of volunteers and non-volunteers due to lack of consent to access the records of non-volunteers.

### Participant flow

Figure 1 illustrates the recruitment and loss of participants to the trial. Table 1 gives a breakdown of reasons for exclusion or loss following delivery. Due to room availability, late notification or early discharge 17 mothers-infant dyads were filmed on only one night (9 missed 1<sup>st</sup> night, 8 missed 2<sup>nd</sup> night).

Figure 1 Recruitment and exclusion of participants.

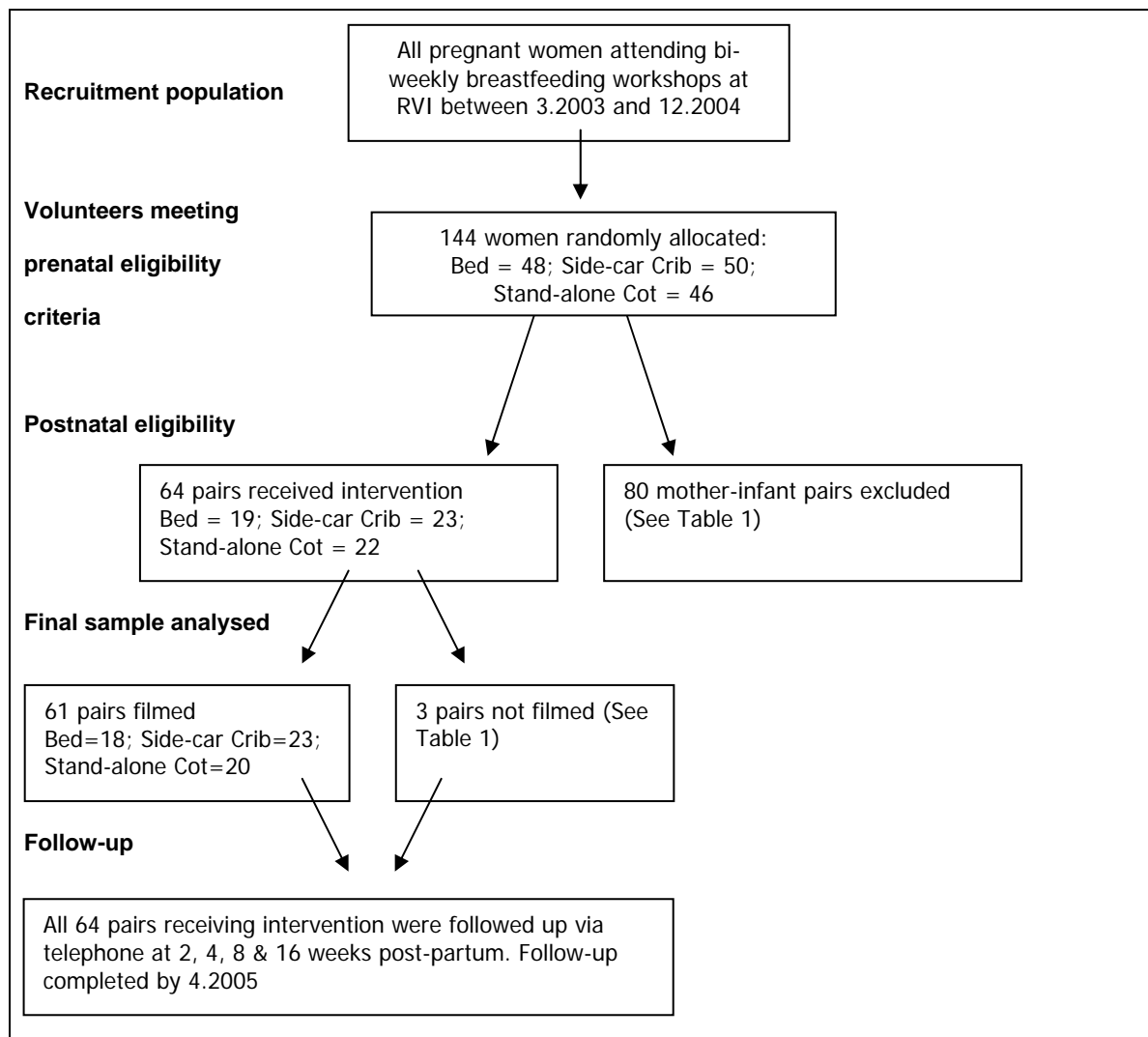


Table 1: Reasons for participant exclusion and ineligibility between enrolment and delivery

144 participants enrolled -- Randomly allocated to:			
	Bed=48	Side-car crib=50	Stand-alone cot=46
Exclusion following delivery:			
C-section	9	14	12
Participant withdrew	1	3	5
Opiate analgesia	3	3	1
Baby unwell	1	0	1
Stillbirth	1	0	0
Mother unwell	1	0	0
<i>Total excluded</i>	<i>16</i>	<i>20</i>	<i>19</i>
Ineligible mothers:			
No camera available	2	1	0
No single room available	7	5	3
Missed notification of delivery	4	1	2
<i>Total ineligible</i>	<i>13</i>	<i>7</i>	<i>5</i>
Total excluded/ineligible	29	27	24
Total eligible participants	19	23	22
<b>Total eligible &amp; videoed</b>	<b>18 dyads</b>	<b>23 dyads</b>	<b>20 dyads</b>

All 61 mothers who participated in filming were interviewed before discharge. A comparison of eligible and ineligible participants found no statistical differences in maternal age, marital status, education and income.

Compliance with the allocated sleeping condition was defined as the infant spending greater than 50% of observed sleep time in the allocated condition per night. Of the 61 participants eligible for analysis, 5 did not comply with their allocated condition on both nights, while a further 14 did not comply on one night. All 61 videoed participants were analysed according to their randomly allocated condition (Intention to Treat Analysis) regardless of cross-over. Participants who crossed-over from bed to stand-alone cot, side-car crib to bed, and stand-alone cot to bed did so of their own preference. Baseline demographic and clinical characteristics of the three intervention groups are provided in Table 2.

Table 2: Characteristics of the three randomised groups that were videoed.

	Mother's Bed (n=18)	Side-car Crib (n=23)	Stand-alone Cot (n=20)
Mean maternal age [years] (range)	32.8 (28-39)	31.4 (21-40)	30.9 (22-37)
Mean infant age at filming [hours] (range)	15.4 (3.5-26)	16.6 (6.8-27.5)	17.6 (6.5-28)
Mean gestation length [days] (range)	283.9 (268-298)	283.2 (270-293)	280.6 (263-292)
Mean birth weight [kg] (range)	3.3 (2.8-4.0)	3.4 (2.6-4.3)	3.5 (2.9-4.3)
Ethnicity n (%)			
White European	16 (89%)	22 (96%)	29 (95%)
Asian	2 (11%)	1 (4%)	1 (5%)
Labour n (%)			
Spontaneous	16 (89%)	17 (77%)	16 (80%)
Induced	2 (11%)	5 (22%)	4 (20%)
Median 5 min APGAR (range)	9 (8-10)	9 (9-10)	9 (9-10)
Median time at delivery since previous maternal sleep [hours] (range)	36.0 (20-60)	36.0 (4-96)	36.0 (12-72)
Median duration of maternal sleep post-delivery before filming [hours] (range)	0.3 (0-8)	1.3 (0-8)	0.8 (0-6)
Mean duration of initial breastfeeding opportunity on delivery suite [mins] (range)	25.0 (5-60)	19.0 (5-90)	23.0 (5-35)

**Primary outcomes**

We analysed data by 'intention to treat'. As shown in Table 3 mothers and babies allocated to the bed and side-car crib conditions made significantly more attempts to feed (both successful and unsuccessful); and exhibited more feeding effort, than babies allocated to the stand-alone cot, but there was no difference between infants allocated to the bed and side-car crib.

None of the 61 infants experienced adverse events or side effects in the course of this study. However we observed potential risk-events for 2 of the 6 pre-defined hypothetical risk categories: breathing risk and falling risk. Potential breathing risk, but not falling risk, was recorded significantly more frequently and for a significantly greater duration, in the bed condition, than in the side-car crib or stand-alone cot conditions.



Table 3: Breastfeeding outcome and potential risk events by allocated sleep condition.

	Bed n=18	Side-car crib n=23	Stand-alone cot n=20	Bed vs Stand-alone cot		Side-car crib vs Stand-alone cot		Bed vs Side-car crib	
	Median frequency per hour (range)			Mean difference (95% CI)	p (Mann-Whitney U)	Mean difference (95% CI)	p (Mann-Whitney U)	Mean difference (95% CI)	p (Mann-Whitney U)
Attempted feeds	1.3 (0.0-11.5)	2.1 (0.0-9.1)	0.7 (0.0-6.9)	1.87 (0.63-3.11)	0.012	1.57 (0.58-2.57)	0.008	0.30(-1.12-1.72)	0.64
Successful feeds	1.2 (0.0-6.0)	1.3 (0.0-7.3)	0.5 (0.0-6.6)	0.90 (0.19-1.61)	0.003	0.96 (0.18-1.73)	0.013	-0.06(-0.95-0.83)	0.93
Feeding effort	2.5 (0.0-17.5)	3.4(0.0-14.3)	1.3 (0.0-12.9)	2.56 (0.72-4.41)	0.008	2.52 (0.87-4.17)	0.006	0.04(-2.10-2.18)	0.97
All potential risk	0.0 (0.0-1.0)	0.0 (0.0-1.2)	0.0 (0.0-0.6)	0.13 (0.03-0.23)	0.100	0.04 (-0.03-0.12)	0.196	0.09 (-0.03-0.21)	0.006
Breathing risk	0.0 (0.0-1.0)	0.0 (0.0-0.6)	0.0 (0.0-0.6)	0.11 (0.01-0.21)	0.158	0.02 (-0.03-0.07)	0.328	0.09 (-0.01-0.19)	0.027
Falling risk	0.0 (0.0-0.5)	0.0 (0.0-0.6)	0.0 (0.0-0.0)	0.02 (-0.01-0.06)	0.858	0.02 (-0.12-0.06)	0.166	0.002 (-0.05-0.51)	0.125
	Median proportional (%) duration (range)								
All potential risk	0.0 (0.0-13.3)	0.0 (0.0-2.3)	0.0 (0.0-6.0)	1.03 (-0.07-2.12)	0.145	-0.05 (-0.40-0.30)	0.118	1.08 (0.06-2.10)	0.007
Breathing risk	0.0 (0.0-13.3)	0.0 (0.0-1.3)	0.0 (0.0-6.0)	0.92 (-0.16-1.99)	0.130	-0.12 (-0.44-0.21)	0.355	1.04 (0.05-2.02)	0.030
Falling risk	0.0 (0.0-0.5)	0.0 (0.0-0.2)	0.0 (0.0-0.0)	0.02 (-0.02-0.06)	0.835	0.01 (-0.00-0.02)	0.166	0.01 (-0.02-0.05)	0.125

**Other outcomes**

Maternal and infant sleep duration, maternal satisfaction and the amount of staff contact time with the mother were analysed (see Table 4). The median proportional sleep duration (range) for mothers was 64.5% (11.8-99.8) and for infants was 65.9% (6.5-99.8). Maternal satisfaction scores were below the mid-point of the scale for mothers allocated to the stand-alone cot condition, and above the mid-point for mothers allocated to the bed and side-car crib conditions, but none of the differences were significant. We assessed demands on staff time in three ways: frequency per hour of calls to staff made by mothers, frequency per hour of visits to mothers by ward-staff, and duration of staff visits. Mothers allocated to the bed and side-car crib conditions called staff significantly more frequently than mothers allocated to the stand-alone cot condition; however we found no differences in the frequency or duration of visits to mothers initiated by staff.

Table 4: Comparison of sleep, satisfaction and staff time across 3 sleeping conditions

	Bed n=18	Side-car crib n=23	Stand-alone cot n=20	Bed vs Stand-alone cot		Side-car crib vs Stand-alone cot		Bed vs Side-car crib	
	Median proportional duration (range)			Mean difference (95% CI)	p (M-W U)	Mean difference (95% CI)	p (M-W U)	Mean difference (95% CI)	p (M-W U)
Maternal sleep duration	59.4 (18.7-98.2)	65.6 (11.8-98.2)	66.7 (12.5-99.8)	-0.29 (-11.0-10.4)	0.499	-5.26 (-15.8-5.2)	0.287	4.97 (-4.6-14.6)	0.642
Infant sleep duration	64.6 (20.6-99.8)	66.6 (6.5-98.1)	67.2 (22.8-98.6)	-2.87 (-13.5-7.7)	0.962	-5.29 (-16.0-5.4)	0.375	2.42 (-8.3-13.1)	0.513
Maternal satisfaction	Mean score (SD)			p (t test)		p (t test)		p (t test)	
	3.1(1.1)	3.2 (0.9)	2.8 (0.8)	0.39 (-0.2-1.0)	0.217	0.46 (-0.9-1.0)	0.096	-0.08 (-0.7-0.6)	0.820
	Mean frequency per hour (SD)			p (t test)		p (t test)		p (t test)	
Calls to staff (Frequency/hr)	0.13 (0.2)	0.17 (0.3)	0.03 (0.1)	0.10 (0.02-0.2)	0.017	0.14 (0.03-0.24)	0.010	-0.03 (-0.2-0.1)	0.617
Visits by staff (frequency/hr)	0.40 (0.5)	0.35 (0.6)	0.28 (0.7)	0.12 (-0.17-0.41)	0.401	0.06 (-0.22-0.35)	0.654	0.05 (0.2-0.3)	0.657
	Mean proportional duration (SD)			p (t test)		p (t test)		p (t test)	
Duration of visits by staff	2.12 (3.6)	1.25 (1.9)	1.05 (3.6)	1.1 (-0.7-2.8)	0.233	0.20 (-1.1-1.6)	0.763	0.87 (-0.5-2.2)	0.205

## DISCUSSION

The results of this randomised trial of three infant sleep locations on the postnatal ward illustrate the benefits of unhindered mother-infant contact on the initiation of breastfeeding over the immediate postnatal period. Mothers and infants experiencing unhindered opportunity for night-time breastfeeding demonstrated greater breastfeeding effort, both in attempting to feed, and feeding successfully more often, than when the infants were physically separated by being in a plastic bassinet (stand-alone cot).

The importance of the frequency of both successful and unsuccessful feeding attempts in the early post-natal period has long been recognised as a key factor in establishing milk production, and in learning how to suckle,[2, 12-14] with the frequency of night-time feeds being of particular significance.[15] High prolactin levels are critical for breastfeeding initiation, and successful long-term lactation depends on the development of sufficient prolactin receptors during this initial period – which depends upon frequent feeding.[16] Any intervention that increases feeding frequency in the early post-partum period, therefore, has the potential to affect not just breastfeeding initiation, but also long-term breastfeeding duration (see [17]).

Regarding infant safety, we found that infants were exposed to potentially hazardous situations (in the form of airway covering) more frequently when allocated to their mothers' beds than when allocated to the side-car crib or stand-alone cot. It is important to acknowledge that all situations identified as potential risks were made using the judgement of the observers coding the video tapes, and it is possible that episodes appearing to be a risk on camera may have seemed otherwise from the vantage point of someone in the room. This possibility is supported by the observation that during one episode coded as a potential risk (due to a mother's arm apparently resting across her infant's face) a midwife entered the room, checked on the sleeping pair, and left again. What appeared as a risk from our camera angle did not seem to alarm the midwife; however the event remained in the coded data as a potential risk, and therefore contributed to the final outcomes.

We also emphasise that as we observed no actual risks, we have no means of assessing the likelihood of a potential risk becoming a real one; none of the infants in this study experienced any adverse effects relating to their experience of potential risks. The infant allocated to the bed condition who experienced the greatest frequency of potential breathing risks was a cross-over from the bed to the stand-alone cot, whose observed bouts of airway covering all occurred while sleeping in the stand-alone cot and were all related to swaddling. This demonstrates that the stand-alone cot environment is not free of potential hazards.

Other analysis of maternal and infant sleep duration on the 1<sup>st</sup> and 2<sup>nd</sup> post-natal nights revealed no differences in sleep duration across conditions. Despite the common argument that mothers need an uninterrupted night's sleep following delivery in order to aid recuperation, two studies [18, 19] found that rooming-in mothers obtained no more or less sleep on their initial postpartum nights than did mothers whose infants were consigned to a hospital nursery. To this we can now add further evidence that the degree of mother-infant proximity does not impact upon post-natal sleep duration, even to the point of the infant sharing the mother's bed.

We acknowledge that it is normal practice in randomised trials that all participants who are allocated to a randomised condition are followed up and included in the data analysis, regardless of whether they subsequently dropped out of the trial. However in this study, due to the ethical requirement that mothers be randomised prior to delivery, we experienced a

high post-randomisation exclusion rate due to delivery and postnatal factors, so we confined the analysis to the actual participants. This has the potential to bias the results if the exclusions disproportionately cluster in certain randomised groups. Analysis of the effects of the exclusions on the overall sample resulted in the study having lower power than originally intended, but as the exclusions were equally distributed across the randomly allocated conditions no disproportionate clustering could be observed. The results may still reflect bias if the exclusions differed from the participants in some systematic way that we have been unable to assess.

The results of this study can only be generalised to mothers and infants experiencing vaginal deliveries without receipt of opiate analgesia in the preceding 24 hours. The effect of opiates upon infant behaviour is known to be profound,[20-23] and we were sufficiently wary of their effects on maternal awareness to consider the use of opiates within 24 hours to be a contraindication for either of the bedding-in conditions.[24] Likewise these results cannot be generalised to mothers and infants experiencing caesarean section delivery due to the complicating effects of caesarean section on breastfeeding initiation, mother-infant interaction, and maternal sleep.[25-27]

As equally frequent feeding took place in both the side-car crib and mother's bed; and the potential for infant risks was equally low for both side-car crib and stand-alone cot, the side-car crib emerges from this study as the most effective post-natal ward sleeping environment for infants in optimising both breastfeeding initiation and infant safety. Bedding-in with the infant in the mother's bed was effective in breastfeeding initiation. Limitations of the fixed camera-angle used in this study in facilitating assessment of potentially hazardous events means that the bed-condition may be shown to be an equally sound option with further study. Future studies to examine the effects on breastfeeding duration from the postnatal use of a side-car crib, and on breastfeeding initiation in groups of mothers with high rates of breastfeeding failure (such as caesarean section) are underway.

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## FIGURE LEGENDS

Figure 1: Recruitment and loss of participants

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